US Army Medical Research and Materiel

Technology Available for Licensing

Encapsulated High-concentration Lipid A Compositions as Immunogenic Agents to Produce Human Antibodies to Prevent or Treat Gram-negative Bacterial Infections

Features and advantages:

- **Injection induces high levels of antibodies against lipid A without causing toxicity in humans**
- **Uses pharmaceutically-acceptable encapsulating slow-releasing delivery materials**
- **Could give in conjunction with therapeutic measures or antibiotics to those at risk for sepsis**
- **Could potentially be monoclonal or polyclonal antibodies**

This invention provides an encapsulated, high-concentration lipid A composition for the treatment and prevention of Gram-negative bacterial infections. It can produce high titers of antibodies in humans. The approach is based on the fact that lipid A is a major element of the lipopolysaccharide molecules that coat the surface of nearly all Gram-negative bacteria.

Gram-negative bacteria are ubiquitous to the environment and also naturally occur in high concentrations in human intestinal tracts. These bacteria cause skin infections and opportunistic infections in association with other afflictions (traumatic injuries; burns; debilitation from old age; and chronic diseases). Sepsis resulting from infection with Gram-negative bacteria is the most common cause of death in hospitals. Current treatments are proving ineffective due to the emergence of antibiotic resistant strains.

The composition was tested in a candidate malaria [illegible]. When increasing doses of undiluted liposomal Lipid A were injected into humans, high levels of IgG antibodies were apparent at the time of first bleeding (two weeks). No significant acute toxic effects were observed.

Patent Status

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